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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/875,456
Filing Date	June 6, 2001
First Named Inventor	Qin
Group Art Unit	1653
Examiner Name	
Attorney Docket Number	ORT-1448

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FOREIGN PATENT DOCUMENTS Foreign Patent Document Date of Publication Pages, Columns, Lines, of Cited Document where relevant Name of Patentee or T⁶ passages or relevant Examiner Cite mm-dd-yyyy Applicant of Cited Document Initials KindCode⁵ figures appear No.1 Office³ Number⁴ 09/03/1998 wo 98/38302 . A2 Hoffmann-La Roche AG 04/05/2001 wo 01/23570 A2 Ortho-McNeil Pharmaceutical, Inc wo 01/23571 A1 University of Michigan 04/05/2001

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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
1		MORAN, OSCAR, et al., "Endogenous expression of the B1A sodium channel subunit in HEK-293 cells," FEBS Letters (2000) Vol 473, No 2 Pages 132-134	
N		MAKITA, Naomasa et al., "Homo sapiens sodium channel beta-1 subunit (SCN1B) mRNA, complete cds.," Database EM HUM ID HSVGSC1B, AC L16242 XP-002193421 (1994)	
- W		MAKITA, Naomasa et al., "Voltage-gated Na+ channel beta 1 subunit mRNA expressed in adult human skeletal muscle, heart, and brain is encoded by a single gene," Journal of Biological Chemistry (1994) Vol 275, No 2 Pages 7571-7578 XP-002145888	
		KAZEN-GILLESPIE, K.A. et al., "Rattus norvegicus voltage-gated sodium channel subunit beta1-A (SCN1B) mRNA, alternatively-spliced, complete cds," Database EM RO ID AF182949, AC 182949 XP-002193422 (2000). —	
4/		SOARES, NSF, "Homo sapiens cDNA clone," Database EM EST ID AI742310, AC AI742310 XP-002193423 (1999)	
		DOE JOINT GENOME INSTITUTE, "Homo sapiens chromosome 19 clone CTD-2527I21, Working Draft Sequence, 13 unordered pieces," Database EM HTG ID AC020907, AC AC020907 XP-002193424 (2000)	
N		DIB-HAJJ, Sulayman D. et al., "Genes encoding the beta-1 subunit of voltage-dependent Na+ channel in rat. mouse and human contain conserved introns," FEBS Letters (1995) Vol 377, No 3 Pages 485-488 XP-002193420	
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J.S. PATENT DOCUMENTS

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner 's Initials *	Cit e No.	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
2	1	BALSER, JEFFREY R, "Structure And Function Of The Cardiac Sodium Channels," Cardiovascular Besearch (1999) 42:327-338	,ـــــ
~	2	CATTERALL, William A., "Cellular And Molecular Biology Of Voltage-Gated Sodium Channels," Pharmaceutical Rev." (1992) 72 (4) S15-S48	
	3	CATTERALL, William A., "Structure And Function Of Voltage-Gated Ion Channels", Trends Neurosci (1993) 16:500-506	
	-4	CHABAL, Charles, Et Al., "The Effect Of Intravenous Lidocaine, Tocainide, And Mexiletine On Spontaneously Active Fibers Originating In Rat Sciatic Neuromas, Pain," (1989) 38:333-338	
~	5	CHAPLAN, S.R., et al., "QUANTITATIVE ASSESSMENT OF TACTILE ALLODYNIA IN THE RAT PAW," JOURNAL OF NEUROSCIENCE METHODS (1994) 53:55-63	_
2	6	D'ANDREA, MICHAEL R., et al. "CHARACTERIZATION OF PROTEASE-ACTIVATED RECEPTOR-2 IMMUNOREACTIVITY IN NORMAL HUMAN TISSUES," JOURNAL OF HISTOCHEMISTRY & CYTOCHEMISTRY, (1998) VOL. 46(2): 157-164	-
.: Q	7	DEVOR, MARSHALL et. al., "NA+ CHANNEL ACCUMULATION ON AXOLEMMA OF AFFERENT ENDINGS IN NERVE END NEUROMAS IN APTERONOTUS," NEUROSCIENCE LETTERS, 102 (1989) 149-154	_
12	8	DEVOR, MARSHALL, "THE PATHOPHYSIOLOGY OF DAMAGED PERIPHERAL NERVES, IN TEXTBOOK OF PAIN." eds Wall PD. Metzack R., (Churchill Livingstone, Edinburgh) 2nd ED, (1994) pp.79-101	
2	9	DEVOR, MARSHALL, et al., "SYSTEMIC LIDOCAINE SILENCES ECTOPIC NEUROMA AND DRG DISCHARGE WITHOUT BLOCKING NERVE CONDUCTION, PAIN," (1992) 48:261-268	
2	10	DIB-HAJJ, et al. "Down-Regulation of Transcripts for Na Channel α-SNS IN SPINAL SENSORY NEURONS FOLLOWING AXOTOMY," Proc. Natl acad. Sci. (USA) (1996) Vol. 93:14950-14954.	
2	11	ECKER, DAVID J., et al., "Increasing Gene Expression In Yeast By Fusion To Ubiquitin," Journal of Biological Chemistry (1989) Vol. 264, 7715-7719	1
7	12	ENGLAND JD, et al, "Sodium channels accumulate at the tips of injured axons." Muscle Nerve (1994) 17:593-598.	_
9	13	ENGLAND, J.D., et al. "Sodium Channel Accumulation In Humans With Painful Neuromas," American Academy of Neurology, (1996) 47:272-276.	
2	14	GOULD, HARRY J. III, et al., "Rapid Sodium Channel Augmentation In Response To Inflammation Induced By Complete Freund's Adjuvant," Brain Research (1998) 802:69-74	1
2	15	HOROWITZ, et al, "Synthesis And Assembly Of Functional Mammalian Na,K-Atpase In Yeast," Journal of Biological Chemistry (1990) 265:4189-4192	٢
a	16	ISOM, L.L., et al. "Primary Structure And Functional Expression Of The β ₁ Subunit Of The Rat Brain Sodium Channel," Science (1992) Vol. 256:839-842	
	17	ISOM, L.L., et al. "Structure And Function Of The β2 Subunit Of Brain Sodium Channels, A Transmembrane Glycoprotein With A Cam Motif," Cell, (1995) Vol. 83:433-442	<u> </u>

Examiner Signature	Thu n	Date Considered	7-17-0)
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ORT-1448	0
	09/875,456 June 6, 2001 Qin, et al.

2	18	ISOM, L.L., et al. "AUXILIARY SUBUITS OF VOLTAGE-GATED ION CHANNELS," Neutron, (1994), Vol 12 1183-1194	-
1	19	JACOBSON, et al., "Expression And Secretion Of Biologically Active Echistatin In Saccharomyces Cerevisiae," Gene (1989) 85:5II-516	
1	20	KITTS, PAUL A., et al., "Linearization Of Baculovirus DNA Enhances The Recovery of Recombinant Virus Expression Vectors." Nucleic Acids Research (1990), 5667-5672	
1	21	MARBAN, et. al., "Structure And Function Of Voltage-Gated Sodium Channels," Journal of Physiology (1998), 647-657	
	22	MATZNER et al., "Na+ Conductance And The Threshold For Repetitive Neuronal Firing," Brain Research (1992) 92-98	
~	23	MATZNER O, et al., "Hyperexcitability at sites of nerve injury depends on voltage-sensitive Na+ channels," J Neurophysiol (1994) 72:349-359.	-
2	24	MCDONNELL, D. et.al., "RECONSTRUCTION OF THE VITAMIN D-RESPONSIVE OSTEOCALCIN TRANSCRIPTION UNIT IN SACCHAROMYCES CEREVISIAE," Molecular & Cellular Biology, Vol.9 No. 8: 3517-3523 (1989)	
	25	NORDIN, et al., "ECTOPIC SENSORY DISCHARGES AND PARESTHESIAE IN PATIENTS WITH DISORDERS OF PERIPHREAL NERVES, DORSAL ROOTS AND DORSAL COLUMNS," Pain 20 (1984), 231-245	
2	26	OCHOA, et al., "PARAESTHESIAE FROM ECTOPIC IMPULSE GENERATION IN HUMAN SENSORY NERVES," Brain (1980) 103, 835-853	-
	27	OH, YOUNGSUK, et al., "Na+ Channel β1 SUBUNIT mRNA; DIFFERENTIAL EXPRESSION IN RAT SPINAL SENSORY NEURONS," Molecular Brain Research, 30 (1995) 357-361	/
2	28	OMANA-ZAPATA, IMELDA, et al., "Tetrodotoxin Inhibits Neuropathic Ectopic Activity In Neuromas, Dorsal Root Ganglia And Dorsal Horn Neurons," Pain 72 (1997) 41-49	-
2	29	PORRECA, FRANK, et al., "A Comparison Of The Potential Role Of The Tetrodotoxin-Insensitive Sodium Channels, Pn3/Sns And Nan/Sns2, In Rat Models Of Chronic Pain," Proc. Natl. Acad. Sci., USA, Vol. 96 (1999) 7640-7644	
9	30	RIEHL-BELLON, NADINE et al., "Purification And Biochemical Characterization Of Recombinant Hirudin Produced By Saccharomyces Cerevisiae," Biochemistry 28 (1989) 2941-2949	-
	31	RINAS, URSULA, et al., "CHARACTERIZATON OF RECOMBINANT FACTOR XIIIa PRODUCED IN SACCHAROMYCES CEREVISIAE," Biotechnology June (1990), 543-546	
	32	RIZZO, MARCO A., "Successful Treatment Of Painful Traumatic Mononeuropathy With Carbamazepine; Insights Into A Possible Molecular Pain Mechanism," Journal of Neurological Sciences, 152 (1997) 103-106	
~	33	SABIN, E. et al., "High-Level Expression And In Vivo Processing Of Chimeric Ubiquitin Fusion Proteins In Saccharomyces Cerevisiae," Biotechnology (1989) Vol. 7: 705-709	
N	34	SLEEP, D, et al., "The Secretion Of Human Serum Albumin From The Yeast Saccharomyces Cerevisiae Using Five Different Leader Sequences," Biotechnology, (1990) Vol., 8:42-45	
~	· 35	SUTKOWSKi et al.," β1 Subunits Of Sodium Channels," The Journal of Biological Chemistry 265 (1990)12393-12399	-
	36	TANAKA, M., et al., "Sns Na+ Channel Expression Increases In Dorsal Root Ganglion Neurons In The Carrageenan Inflammatory Pain Model," Molecular Neuroscience, (1998) Vol. 9:967-972	

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Examiner Signature	Ja un	Date Considere	red 7-31-03
	9		

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	37	WALLACE, R. H., et al., "Febrile Seizures And Generalized Epilepsy Associated With A Mutation In The Na+Channel β1 Subunit Gene Scn1b," Nature Genetics 19 (1998) 366-370	-
	38	WAXMAN, STEPHEN, et al., "Conductin Through Demyelinated Plaques In Multiple Sclerosis; Computer Simulations Of Facilitation By Short Internodes," Journal of Neurology, Neurosurgery, and Psychiatry 41 (1978) 408-416	
1/	39	WAXMAN, S.G., et al., *Sodium Channels And Pain, *Proc. Natl. Acad. Sci, USA, 1999 Vol 96, 7635-7639	
	40	WAXMAN SG, et al. "Type III Sodium Channel mRNA is Expressed in Embryonic But Not Adult Spinal Sensory Neurons, And is Reexpressed Following Axotomy," J Neurophysiol 72:466-470(1994)	-
2	41	YAMAMOTO, YOSHIO et al., "Important Role Of The Proline Residue In The Signal Sequence That Directs The Secretion Of Human Lysozyme In Saccharomyces Cerevisiae," Biochemistry (1989), 28:2728-2732	/
2	42	DEVEREUX, J. et al., "A Comprehensive Set Of Sequence Analysis Programs For The Vax", Nucleic Acids Research, (1984) Vol. 12:387-395,	_
W	43	ISOM & CATTERALL, "Na+ Channel Subunits And Ig Domains," Nature (1996) Vol. 383:307-308	_
2	44	KAUFMAN, R.J., et al., "Amplification and Expression of Sequences Cotransfected with a Modular Dihydrofolate Reductase Complementary DNA Gene," J. Mol. Biol. (1982) Vol. 159:601-621	_
	45	TAGLIALATELA, M., et al., "Novel Voltage Clamp To Record Small, Fast Currents From Ion Channels Epressed In Xenopus Oocytes," Biophys. J. (1992) Vol. 61:78-82	_
	46	WIGLER, M., et al., "Transfer of Purified Herpes Virus Thymidine Kinase Gene to Cultured Mouse Cells," Cell (1977) Vol. 11:223-232	-
	47	KAZEN-GILLESPIE, K. A. et al., "Cloning, Localization, and Functional Expression of Sodium Channel β1A Subunits", Journal of Biological Chemistry (2000) Vol. 275:1079-1088	
/	48	KIM, SUN HO and CHUNG, JIN MO, "An experimental model for peripheral neuropathy produced by segmental spinal nerve ligation in the rat" Pain 50 (1992) 355-363	/
	1 623		

Examiner Signature	Date Considered	3-31-0)	
	 		

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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
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Initials*	No.1	publisher, city and/or country where published	
		BALSER, JEFFREY R, STRUCTURE AND FUNCTION OF THE CARDIAC SODIUM CHANNELS, Cardiovascular Research	
		(1999) 42:327-338	<u> </u>
10 -	L	Catterall, William A., CELLULAR AND MOLECULAR BIOLOGY OF VOLTAGE-GATED SODIUM CHANNELS,	1
		Pharmaceutical Rev., Vol. 22, No. 4 (1991) William A., STRUCTURE AND FUNCTION OF VOLTAGE-GATED ION	
	<u> </u>	CHANNELS, Trends Neurosci 16:5–506 (1993) Chabal, Charles, et al., THE EFFECT OF INTRAVENOUS LIDOCAINE, TOCAINIDE, AND MEXILETINE ON	
		SPONTANEOUSLY ACTIVE FIBERS ORIGINATING IN RAT SCIATIC NEUROMAS, Pain, 38 (199) 333-338	
		Chaplan, S.R., et al., QUANTITATIVE ASSESSMENT OF TACTILE ALLODYNIA IN THE RAT PAW, Journal of	
<i> </i>		Neuroscience Methods 53 (1994) 55-63	├
		D'Andrea, Michael R., et al. CHARACTERIZATION OF PROTEASE-ACTIVATED RECEPTOR-2 IMMUNOREACTIVITY IN	
	L	NORMAL HUMAN TISSUES, Journal of Histochemistry & Cytochemistry, Vol. 46(2): 157-164 (1998)	_
,		Devor, Marshall et al., NA+ CHANNEL ACCUMULATION ON AXOLEMMA OF AFFERENT ENDINGS IN NERVE END	
		NEUROMAS IN APTERONOTUS, Neuroscience Letters, 102 (1989) 149-154	
()	İ	Devor, Marshall, THE PATHOPHYSIOLOGY OF DAMAGED PERIPHERAL NERVES, In Textbook of Pain, eds. 79-101	
		(1994) Devor, Marshall, et al. SYSTEMIC LIDOCAINE SILENCES ECTOPIC NEUROMA AND DRG DISCHARGE WITHOUT	
1		BLOCKING NERVE CONDUCTION, Pain, 48 (1992) 261-268	<u>ا</u>
		BEOGRAPO NEIVE CONDUCTION, 1 MII, 40 (1002) 201-200	1
<i>()</i>		Dib-haji, et al. Down-Regulation of Transcripts for Na Channel α-SNS IN SPINAL SENSORY NEURONS FOLLOWING	1
		AXOTOMY, Neurobiology (1996) Vol. 93, 14950-14954.	†
	f -	Ecker, David J., et al., INCREASING GENE EXPRESSION IN YEAST BY FUSION TO UBIQUITIN, Journal of Biological]
~		Chemistry Vol. 264, 7715-7719 (1988)	1
		England JD, Gamboni F, Ferguson MA, Levinson SR (1994) Sodium channels	
		accumulate at the tips of injured axons. Muscle Nerve 17:593-598.	T
y _		England, J.D., et al. (1996) SODIUM CHANNEL ACCUMULATION IN HUMANS WITH PAINFUL NEUROMAS, American	<u> </u>
		Academy of Neurology, 47:272-276. Gould, Harry J. III, et al., RAPID SODIUM CHANNEL AUGMENTATION IN RESPONSE TO INFLAMMATION INDUCED BY	
		COMPLETE FREUND'S ADJUVANT, Brain Research 802 (1998) 69-74	حــا.
7		Horowitz, et al. SYNTHESIS AND ASSEMBLY OF FUNCTIONAL MAMMALIAN Na,K-ATPase IN YEAST, Journal of	<u> </u>
		Biological Chemistry (1990)	7
V /	1	Isom, L.L., et al. PRIMARY STRUCTURE AND FUNCTIONAL EXPRESSION OF THE β1 SUBUNIT OF THE RAT BRAIN	
()		SODIUM CHANNEL, Science (1992), Vol. 356.	<u> </u>
· ~	ł	ISOM, LL, et al. STRUCTURE AND FUNCTION OF THE β2 SUBUNIT OF BRAIN SODIUM CHANNELS, A	1-
0	<u> </u>	TRANSMEMBRANE GLYCOPROTEIN WITH A CAM MOTIF, Cell, Vol. 83 (1995) 433-442	<u> </u>
	 	ISOM, L.L., et al. AUXILIARY SUBUITS OF VOLTAGE-GATED ION CHANNELS, Neutron, (1994), Vol 12 1183-1194	
' <i>}</i> -	ĺ	Jacobson, et al., EXPRESSION AND SECRETION OF BIOLOGICALLY ACTIVE ECHISTATIN IN SACCHAROMYCES CEREVISIAE, Gene (1989) 51-516	-
	 	KAZEN-GILLESPIE, et al., CLONING, LOCALIZATOIN, AND FUNCTIONAL EXPRESSION OF SODIUM CHANNEL B1A	
	1	SUBUNITS, Journal of Biological Chemistry (2000) Vol. 275 No. 2 1079-1088	†
7	 -	Kim, et al. AN EXPERIMENTAL MODEL FOR PERIPHERAL NEUROPATHY PRODUCED BY SEGMENTAL SPINAL	1
		NERVE LIGATION IN THE RAT, Pain (1992), 355-363	1
		Kitts, Paul A., et al., LINEARIZATION OF BACULOVIRUS DNA ENHANCES THE RECOVERYOF RECOMBINANT VIRUS	
	ļ	EXPRESSION VECTORS, Nucleic Acids Research (1990), 5667-5672	<u> </u>
	ł	Marban, et al., STRUCTURE AND FUNCTION OF VOLTAGE-GATED SODIUM CHANNELS, Journal of Physiology (1998),	_
<u> </u>	 	647-657 Matzner et al., Na+ CONDUCTANCE AND THE THRESHOLD FOR REPETITIVE NEURONAL FIRING, Brain Research	1
		Maizner et al., Na+ CONDUCTANCE AND THE THRESHOLD FOR REPETITIVE NEURONAL FIRING, Brain Research (1992) 92-98	Į.
		Matzner O, Devor M (1994) Hyperexcitability at sites of nerve injury depends on	†
	1	voltage-sensitive Na+ channels. J Neurophysiol 72:349-359.	1
		1 1010000 Domotorio va. omminora, a nograbilizata inicis ansi	1

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Application Number	09/875,456
Filing Date	June 6, 2001
First Named Inventor	Qin, et al.
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	MCDONNELL, D. et al. RECONSTRUCTION OF THE VITAMIN D-RESPONSIVE OSTEOCALCIN TRANSCRIPTION UNIT IN SACCHAROMYCES CEREVISIAE, Molecular & Cellular Biology, (1989) Vol.9 No. 8: 3517-3523	_
2	NORDIN, et al., ECTOPIC SENSORY DISCHARGES AND PARESTHESIAE IN PATIENTS WITH DISORDERS OF PERIPHREAL NERVES, DORSAL ROOTS AND DORSAL COLUMNS, Pain 20 (1984), 231-245	-
2	OCHOA, et al., PARAESTHESIAE FROM ECTOPIC IMPULSE GENERATION IN HUMAN SENSORY NERVES, Brain (1980) 103, 835-853	•
	Oh, Youngsuk, et al., Na+ Channel β1 SUBUNIT mRNA; DIFFERENTIAL EXPRESSION IN RAT SPINAL SENSORY NEURONS, Molecular Brain Research, (1995) 357-361	
2	Omana-Zapata, Imelda, et al., TETRODOTOXIN INHIBITS NEUROPATHIC ECTOPIC ACTIVITY IN NEUROMAS, DORSAL ROOT GANGLIA AND DORSAL HORN NEURONS, Pain 72 (1997) 41-49	
~	Porreca, Frank, et al., A COMPARISON OF THE POTENTIAL ROLE OF THE TETRODOTOXIN-INSENSITIVE SODIUM CHANNELS, PN3/SNS AND NAN/SNS2, IN RAT MODELS OF CHRONIC PAIN, Proc. Natl. Acad. Sci., USA, Vol. 96 (1999) 7640-7644	
2	Riehl-Bellon, Nadine et al., PURIFICATION AND BIOCHEMICAL CHARACTERIZATION OF RECOMBINANT HIRUDIN PRODUCED BY SACCHAROMYCES CEREVISIAE, Biochemistry (1989) 2941-2949	
~	Rinas, Ursula, et al., CHARACTERIZATON OF RECOMBINANT FACTOR XIIIa PRODUCED IN SACCHAROMYCES CEREVISIAE, Biotechnology (1990), 543-546	
2	RIZZO, MARCO A., SUCCESSFUL TREATMENT OF PAINFUL TRAUMATIC MONONEUROPATHY WITH CARBAMAZEPINE; INSIGHTS INTO A POSSIBLE MOLECULAR PAIN MECHANISM, Journal of Neurological Sciences, (1997) 103-106	
1/2	SABIN, E. et al., HIGH-LEVEL EXPRESSION AND IN VIVO PROCESSING OF CHIMERIC UBIQUITIN FUSION PROTEINS IN SACCHAROMYCES CEREVISIAE, Biotechnology (1989) Vol. 7: 705-709	
1	Sleep, D, et al., THE SECRETION OF HUMAN SERUM ALBUMIN FROM THE YEAST SACCHAROMYCES CEREVISIAE USING FIVE DIFFERENT LEADER SEQUENCES, Biotechnology, Vol., 8 (1990) 42-45	
	Sutkowski et al., β1 SUBUNITS OF SODIUM CHANNELS, The Journal of Biological Chemistry (1990)12393-12399	
2	Tanaka, M., et al., SNS NA+ CHANNEL EXPRESSION INCREASES IN DORSAL ROOT GANGLION NEURONS IN THE CARRAGEENAN INFLAMMATORY PAIN MODEL, Molecular Neuroscience, vol. 9 (1998) 967-972	
n	Wallace, R. H., et al., FEBRILE SEIZURES AND GENERALIZED EPILEPSY ASSOCIATED WITH A MUTATION IN THE NA+CHANNEL B1 SUBUNIT GENE SCN1B, Nature America Inc. (1998), 368-370-	
~	Waxman, Stephen, et al., CONDUCTIN THROUGH DEMYELINATED PLAQUES IN MULTIPLE SCLEROSIS; COMPUTER SIMULATIONS OF FACILITATION BY SHORT INTERNODES, Journal of Neurology, Neurosurgery, and Psychiatry (1978) 408-416	
	Waxman, S.G., et al., SODIUM CHANNELS AND PAIN, Proc. Natl. Acad. Sci, USA, 1999 Vol 96 7635-7639	
	WAXMAN SG, ET AL. (1994) TYPE III SODIUM CHANNEL MRNA IS EXPRESSED IN EMBRYONIC	
)	BUT NOT ADULT SPINAL SENSORY NEURONS, AND IS REEXPRESSED FOLLOWING AXOTOMY. J NEUROPHYSIOL 72:466-470.	
~	Woolf CJ, et al., (1994) Nerve growth factor contributes to the generation of inflammatory sensory hypersensitivity. Neuroscience 62:327-331.	
2	Yamamoto, Yoshio et al., IMPORTANT ROLE OF THE PROLINE RESIDUE IN THE SIGNAL SEQUENCE THAT DIRECTS THE SECRETION OF HUMAN LYSOZYME IN SACCHAROMYCES CEREVISIAE, American Chemical Society (1989), 2728-2732	
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